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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,768	01/19/2005	Robert Kallmeier	BJS-4145-22	4166

23117 7590 06/27/2007  
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ARLINGTON, VA 22203

EXAMINER
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QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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06/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/521,768

**Applicant(s)**

KALLMEIER ET AL.

**Examiner**

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 0105.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

Claims 9-23 are pending in the application.

#### ***Election/Restrictions***

Applicant's election of Group III in the reply filed on 3/28/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 9-16, 23 are withdrawn from consideration for being directed to non-elected subject matter. Claims 17-22 are currently under examination.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bebbington et al (Biotechnology, 1992. Vol. 10, pages 169-175), in view of de Veillier (US 4,963,481).

Bebbington et al. teach vectors that comprises two transcription units including a first transcription unit that expresses the chimeric light chain gene under the promoter-enhancer of hCMV-MIE, and a second transcription unit that comprises the glutamine synthetase as an amplification marker (see page 171, 1<sup>st</sup> col., 2<sup>nd</sup> paragraph, and Figure 3). However, Bebbington et al. do not teach that the vector comprises mCMV promoter or a functional fragment thereof.

De Velliers et al. teach the nucleotides sequence of murine CMV promoter, and its fragments that can direct strong expression of heterologous gene in a wide range of cell types (see Figure 2, and col.2 last paragraph through col.3 1<sup>st</sup> paragraph). De Velliers et al. teach that the full length promoter 2270 bp, the shorter fragment of 1387 and 196 bp that comprises the Xho I site display strong promoter activity in wide host range, including CHO cell lines (see col.3, 2<sup>nd</sup> paragraph). De Velliers et al. also teach that mCMV hybrid promoters including enhancer from SV40 enhancer or polyomavirus enhancer are found to be exceptionally strong promoter of transcription, particularly in human Hela and CHO cell lines (see lines 1-6 of col.4).

It would have been obvious to one of ordinary skill in the art to use mCMV promoter in the first transcription unit for direct expression in particular cell lines such as CHO based on the teaching of Bebbington and De vellier et al. One of ordinary skill in the art would have been motivated to do so to have strong expression of the heterologous protein of interest in certain cells lines such as CHO because De Vellier et al. teach that mCMV is very effective in direct expression in such cell lines. One of ordinary skill in the art would have been motivated to use mCMV that extends beyond 500 (said fragment certainly comprises transcription start site to – 500 and the XhoI site) because such fragment (i.e. 2270, and 1387) directs strong expression of the heterologous protein. One of ordinary skill in the art would also be motivated to include a

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restriction site after the transcription start site for ease of insertion of a nucleic acid that encodes a gene of interest. Since De Vellier et al. demonstrated that hybrid promoter-enhancer pair such as mCMV and SV40 enhancer promoter directs transcription effectively in Hela and CHO cell lines, one of ordinary skill in the art would have been motivated to include an intron sequence that regulates the transcription effectively based on the type of cell line used for protein expression. The level of molecular cloning is high. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to make a vector that comprises two transcription unit including mCMV as a promoter and glutamine synthetase as an amplification marker. Therefore, the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Claim Objections***

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 is directed to a vector comprising a mCMV promoter that extends upstream to position -500, whereas in claim 19, the promoter is extends to natural Xho I site. This fragment is actually smaller than the 500bp recited in claim 18. As such, it fails to further limit claim 18.

Claims 17-22 are objected for recitation of "vector." It is unclear whether the claimed vector is in singular or plural form. It is suggested to change claim 17 to recite "a mammalian expression vector" and the rest of the claims to recite "The vector according to" to obviate this objection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

